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EXAMINER

BAUM, STUART F

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 12/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/602,840

Applicant(s)

KIRIHARA ET AL.

Examiner

Stuart F. Baum

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 72,73,78,79,84,86,88-91 and 95-110 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 72,73,78,79,84,86,88-91 and 95-110 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The amendment filed 9/25/2003 has been entered.

Claims 72-73, 78-79, 84, 86, 88-91 and 95-110 are pending and are examined in the present office action.

Claim 94 has been canceled.

Rejections and objections not set forth below are withdrawn.

The text of those sections of Title 35, U.S. Code not included in this office action can be found in a prior office action.

#### ***Specification***

The preliminary amendment amending the priority information on the first line of the specification is acknowledged. But, the first line of the specification should be further amended to state that application number 08/763,704 is now U.S. Patent Number 6,326,527.

#### ***Indefiniteness***

Claims 72-73, 78-79, 84, 86, 88-91, and 95-110 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 72, the recitation "augmented" has not been defined. Does Applicant mean that a nucleic acid sequence has been introduced into the genome of a maize plant? This is not an art recognized term and as such, it is not clear if the term incorporates other factors that have not been explicitly stated. All subsequent recitations of "augmented" are also rejected. This

rejection is maintained for the reasons of record set forth in the Official action mailed 5/21/2003.

Applicant's arguments filed 9/25/2003 have been fully considered but they are not persuasive.

Applicants contend that claim terms must be viewed in the context of the claim in which they are found. In the present case, a fertile transgenic *Zea mays* plant has its genome "augmented" by a preselected DNA sequence. Applicants contend that "augmented" refers to genetic transformation in the genome and that the DNA sequence is transmitted through a sexual cycle.

The Office contends that "augmented" is not an art recognized term, as stated in the previous office action. It is not clear if augmentation incorporates other factors that affect the genome while being transmitted to sexually produced offspring. The Office suggests replacing the word "augmented" with --transformed with--.

In claim 72, the metes and bounds of "preselected" have not been defined. It is unclear what is encompassed in a "preselected" DNA sequence. What constitutes a "preselected" DNA sequence? All subsequent recitations of "preselected" are also rejected. This rejection is maintained for the reasons of record set forth in the Official action mailed 5/21/2003.

Applicant's arguments filed 9/25/2003 have been fully considered but they are not persuasive.

Applicants contend that the term "preselected" is not indefinite because it is defined in the online version of the Meriam Webster® dictionary. Applicants recite the definition of the term as "to choose in advance usually on the basis of a particular criterion" (page 10, 1<sup>st</sup> full paragraph).

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The Office contends that the term “preselected” is indefinite because it is not clear what are the criteria that are being used to select a particular sequence. The Office understands the meaning of the word “preselected”, but Applicants have not defined the criteria by which they are selecting a DNA sequence.

In Claim 72, the metes and bounds of “substantially identical” have not been defined. What constitutes a substantial identity? Applicant has not defined the limits by which one skilled in the art would identify a DNA sequence as being “substantially identical”. Would DNA sequences encoding beta- or gamma-zeins be encompassed by Applicant’s claim to “substantially identical” sequences? All subsequent recitations of “substantially identical” are also rejected. This rejection is maintained for the reasons of record set forth in the Official action mailed 5/21/2003. Applicant’s arguments filed 9/25/2003 have been fully considered but they are not persuasive.

Applicants contend that the term “substantially identical” has been defined on page 12, lines 11-24 of the specification and as such, is not indefinite. Applicants contend that the meaning of the term to one of skill in the art is clear, e.g., substantially identical must refer to a preselected DNA sequence encoding an RNA molecule that is sufficiently identical to an mRNA encoding a 19kD or a 22KD  $\alpha$ -zein plant seed storage protein to hybridize with the seed storage protein mRNA in vivo to cause antisense suppression (page 11, top paragraph).

The Office contends that the definition of “substantially identical” as recited in the specification is indefinite. The Applicant does not explicitly state what constitutes a DNA sequence that is “substantially identical” but rather states examples of various percent identities

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that can be used. The Office also contends that the claim as recited by Applicant, does not further define the term “substantially identical”. The claim/definition recites other terms, e.g., preselected, and sufficiently identical, that are indefinite and that do not further explicitly define the term for one skilled in the art.

In claim 88, the metes and bounds of “substantially complementary to all or a portion” have not been defined. Applicant has not defined the limits by which one skilled in the art would identify a DNA sequence as being “substantially complementary to all or a portion”. Applicants recitation reads on one base pair. All subsequent recitations of “substantially complementary to all or a portion” are also rejected.

In claim 90, the metes and bounds of “substantially identical to all or a portion” have not been defined. Applicant has not defined the limits by which one skilled in the art would identify a DNA sequence as being “substantially identical to all or a portion”. Would DNA sequences encoding beta- or gamma-zeins be encompassed by Applicant’s claim to “substantially identical to all or a portion”? All subsequent recitations of “substantially identical to all or a portion” are also rejected. These rejections are maintained for the reasons of record set forth in the Official action mailed 5/21/2003. Applicant’s arguments filed 9/25/2003 have been fully considered but they are not persuasive.

Applicants contend that the term “substantially complementary” and “substantially identical” have been defined on page 12, lines 11-24 of the specification and as such, is not indefinite. Applicants contend that the claims define the terms by indicating that expression of the seed storage protein RNA decreases the amount of seed storage protein (page 11, last

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paragraph). Applicants contend that sequences that are “substantially complementary” or “substantially identical to all or a portion” refers to those sequences that are complementary such as to hybridize with the seed storage protein mRNA in vivo to cause antisense suppression.

The Office contends that the definition of “substantially identical to all or a portion” or “substantially complementary to all or a portion” as recited in the specification is indefinite. The Applicant does not explicitly state what constitutes a DNA sequence that is “substantially identical” or “substantially complementary” but rather states examples of various percent identities that can be used. The Office also contends that the claim as recited by Applicant, does not further define the recited terms. How much suppression is considered “antisense suppression”? Applicants have not stated the metes and bounds of “antisense suppression”.

### *Written Description*

Claims 72-73, 78-79, 84, 86, 88-91, and 95-110 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 5/21/2003. Applicant's arguments filed 9/25/2003 have been fully considered but they are not persuasive.

Applicants contend that they are puzzled by the appearance of the written description rejection in the last office action as it was withdrawn in the final office action in view of the response to the first office action. Applicants contend that the structural features unique to a maize 19 kD and 22 kD  $\alpha$ -zein plant seed storage protein have been fully described in the

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specification. Applicants direct the Examiner's attention to FIG. 1 of the application as well as pages 1-3 of the application. Pages 1-3 describe the family of known zeins, including 19 kD and 22 kD  $\alpha$ -zein and functional domains of the 19 kD  $\alpha$ -zeins. Applicants also contend that the nucleic acid sequences of the A20 and Z4 cDNAs which are species of 19 kD and 22 kD  $\alpha$ -zein protein genes. Applicants contend that Marks et al (1985, stated as being cited on page 5 of the action) demonstrates the common structural characteristics shared among 19 kD and 22 kD  $\alpha$ -zeins. Applicants contend that Marks et al indicates that cDNA sequences among the 19 kD and 22 kD group of  $\alpha$ -zein sequences are 75 to 95% and 92% homologous, respectively. Lastly, Applicants contend that Applicants' disclosure combined with the teachings of Marks et al disclose the structural characteristics of 19 kD and 22 kD  $\alpha$ -zein proteins, which taken together is more than adequate to demonstrate compliance with the written description requirement (pages 12-14, Section D).

The Office contends that the written description rejection was reinstated because the claims are broadly drawn to Zea mays plants transformed with preselected DNA sequences encoding all or a portion of any RNA molecule which is substantially identical or complementary to any mRNA encoding any 19kD or any 22kD  $\alpha$ -zein plant seed storage protein or any seed storage protein. Applicants have only disclosed structural information pertaining to the 19kD and 22kD  $\alpha$ -zein plant seed storage proteins but have not disclosed information pertaining to RNA molecules that are substantially identical or complementary to any mRNA encoding any 19kK or any 22kD  $\alpha$ -zein plant seed storage protein. Other than nucleic acid sequences encoding 19kD and 22kD  $\alpha$ -zein storage proteins, Applicants do not identify any nucleic acid sequences whose mRNA molecules are substantially identical or substantially



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complementary to any mRNA encoding any 19kD or any 22kD  $\alpha$ -zein plant seed storage protein. Applicants fail to describe a representative number of nucleic acid sequences falling within the scope of the genus of RNA molecules which are substantially identical or complementary to any mRNA encoding any 19kD or any 22kD  $\alpha$ -zein plant seed storage protein or any seed storage protein. Applicants have not shown that RNA molecules which are substantially identical or substantially complementary to any mRNA encoding any 19kD or any 22kD  $\alpha$ -zein plant seed storage protein still encodes a protein with the same structural and functional characteristics as a 19kD or a 22kD  $\alpha$ -zein plant seed storage protein.

### ***Enablement***

Claims 72-73, 78-79, 84, 86, 88-91, and 95-110 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 5/21/2003. Applicant's arguments filed 9/25/2003 have been fully considered but they are not persuasive.

The Applicants contend that no basis has been provided to doubt the enablement of the claims. Applicants contend that the Coleman et al reference which was used in the enablement rejection showing that high-lysine mutants exhibit a reduction of  $\alpha$ -zein content concomitant with an inferior endosperm quality actually demonstrates the enablement of the claims.

Applicants contend that the "inferior" endosperm is in fact a *soft and starchy endosperm* [sic].

Applicants contend that the reference shows the direct correlation between increased lysine,

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decreased  $\alpha$ -zein and soft and starchy endosperm. Applicants contend that this correlation supports enablement, given that the Action already acknowledged that Applicants have demonstrated increasing lysine. Applicants further contend that Coleman et al demonstrated successful expression of a 24 kDa  $\alpha$ -zein gene to induce the mutant phenotype provides still further evidence of enablement. Lastly, Applicants note that whether the endosperm is subjectively "inferior" or not is irrelevant to enablement. An "inferior" endosperm does not equate to an inability to increase starch content or extractability, as described in Coleman et al. (page 15, first and second full paragraphs).

The Office maintains that Applicants are not enabled for increasing the starch content or starch extractability of Zea mays seeds. Applicants have only taught how to decrease the amount of the amino acid leucine while increasing the amount of the amino acid lysine. Nowhere in the Coleman et al reference do they state that the starch content of seeds is increased. They only state that Zea mays seeds comprising an increase in lysine content also comprise an inferior endosperm which is soft and starchy. The Office does not interpret this statement to mean that the starch content of the endosperm is increased or that the starch extractability is increased. It appears that Applicants are interpreting this statement as meaning the starch content of the endosperm is increased and that the starch extractability is increased.

The Applicants cite the Marks et al reference in their arguments in support for enablement of the pending claims.

The Office contends that the Marks et al reference was not cited in the enablement rejection of the last office action and as such, Applicants contentions in regards to Marks et al are moot.

Applicants contend that the Moonan (2002) reference is irrelevant to the enablement rejection of the instant claims because the Moonan reference teaches viral protection in sugarcane, whereas Applicants' claims are drawn to *Zea* maize and what is subjectively "inferior" has absolutely nothing to do with enablement. Applicants contend that subjectivity is not pertinent to enablement. Applicants contend that there is not basis to analogize viral protection as taught by Moonan with alteration of function of an endogenous maize gene; the scientific principles are entirely different from that of the claimed invention. Applicants contend that evidence of enablement of the claims is provided at page 83 of the specification. There it is described that endosperm cells in a maize kernel are made up primarily of large starch granules and protein sequestered in protein bodies. Applicants contends that using a zein antisense construct, a reduction in the number of protein bodies in endosperm cells was achieved. Lastly, Applicants contend that a decrease in the amount of seed storage protein is therefore concomitant with an increase in the relative starch content of the kernel.

The Office contends that the Moonan reference is relevant to the instant application because both the reference and the instant application are using antisense technology. It is irrelevant if the plant is sugarcane or *Zea* maize or if the antisense technologies are directed at viral protection or suppression of an endogenous gene, the mechanism is the same. To date, no one has shown that there is a difference in the effectiveness of antisense between one plant and another. The Office contends that the Moonan reference teaches that there is a difference in the efficacy of suppression of a gene using DNA sequences that are less than 100% identical to the target gene. What the Moonan reference teaches is that the efficacy of suppression decreases as the percent identity of the antisense molecule decreases, as compared to the target DNA

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molecule. The Moonan reference teaches target genes are not suppressed when antisense molecules are not 100% sequence identical to the target gene. The rationale for presenting the Moonan reference in the enablement rejection was to demonstrate the unpredictability of antisense when using DNA molecules that are not 100% sequence identical to the target gene. Lastly, the Office contends that Applicants' specification teaches the use of antisense molecules exhibiting 100% sequence identity to a target gene and not antisense molecules that are substantially identical or substantially complementary to any mRNA encoding any 19kD or any 22kD  $\alpha$ -zein plant seed protein.

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 703-305-6997. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Stuart F. Baum Ph.D.

December 8, 2003

  
ELIZABETH F. McELWAIN  
PRIMARY EXAMINER  
GROUP 1800